

510(k) Summary

Trade Name: Coverage Spray HBV

DEC 16 1996 K964835

Common/Usual Name: General Purpose Disinfectant

Submitter/Manufacturer: ConvaTec, Division of E.R. Squibb and Sons, Inc.
5035 Manchester Avenue
St. Louis, MO 63110
Establishment Registration Number: 1940768

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Description: Coverage Spray HBV is a liquid chemical germicide utilizing quaternary ammonium chloride compounds as active ingredients.

Intended Use: Coverage Spray HBV is used to inactivate specific bacteria, fungi and viruses on hard inanimate surfaces including reusable non-critical medical devices and environmental surfaces in healthcare facilities.

Substantial Equivalence to: (1) Tor Germicidal Cleaner, Huntington Laboratories, (2) Quat-Syl 256, National Laboratories, (3) Futron 25, Hysan Corp.

Comparison to Listed Substantially Equivalent Products: Listed products are also liquid chemical germicides utilizing quaternary ammonium chloride compounds as active ingredients to inactivate specific bacteria, fungi, and viruses on hard inanimate surfaces.

Safety Data: Acute Oral LD₅₀ (Rats) = 5,000 mg/kg

Acute Dermal LD₅₀ = > 2,000 mg/kg

Dermal Irritation (Rabbit) neat = Produced mild transient redness and swelling

Eye Irritation (Rabbit) neat = Produced mild transient eye irritation.

Dermal Sensitization (Guinea Pig) = Negative as sensitizer

Effectiveness Data: Germicidal: Approved by EPA against *S. aureus*, *S. choleraesuis* and *Ps. aeruginosa* and other bacteria.

Fungicidal: Approved by EPA against pathogenic fungi and *Aspergillus niger*

Virucidal: Approved by EPA against Hepatitis B Virus, HIV-1, Herpes simplex Type 1 and Type 2 Virus, Parainfluenza Type 1 Virus, Pseudorabies Virus, Influenza A₂ Virus, Influenza B Virus, and Measles Virus